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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,190	06/02/2005	Paolo Corvi Mora	27419-230	1281
7590 NIXON PEABODY LLP Clinton Square P.O. Box 31051 Rochester, NY 14603				
EXAMINER KOSAR, AARON J				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,190

Applicant(s)

CORVI MORA ET AL.

Examiner

AARON J. KOSAR

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 15-18, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 15-18, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment and argument filed March 12, 2008 in response to the non-final rejection, are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn. Applicant has amended the claims by canceling claim 19.

Claims 1-11, 15-18, 20, and 21 are pending and have been examined on the merits.

Specification

The disclosure is objected to because of the following informalities:

The Specification contains the composition C-PROPOFLAVIS which appears to be a trademark/trade name of an apparent propolis-containing material.

A trademark or trade name cannot be used properly to identify any particular material or product, since a trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an alleged propolis component in all of the working examples. As evidenced by CANAL (Canal, T, "Actimex SrP" <<http://www.technoline.area.trieste.it/TenantsData.aspx?IdTenant=67&Action=Data&IdLanguage=2>> (accessed 21 July 2008), 5 pages.), the composition appears to comprise a highly purified propolis extract; however, it is not clear in the record if the composition disclosed in Canal (i.e. C-PROPOFLAVIS) and the composition(s) of the instant Application (i.e. propoflaviv, C-Propoflaviv) are the same chemical compositions.

For the sake of compact prosecution C-PROPOFLAVIS is being treated as a propolis-containing composition (i.e. a highly-purified propolis extract); however, this does not absolve

Applicant of the requirement to appropriately correlate the chemical relationship among propolis and C-PROPOFLAVIS.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

MPEP § 2163 states that, “[n]ew or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).” Further, the MPEP states, “[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.”

In the instant case, the term *amino acid*₂ amended the scope of the claims from an amino acid. However, it is noted that the specification does not provide for multiple amino acids and the disclosed species of an amino acid composition cannot provide support for all combinations of amino acids embraced by the amended claim. Additionally, there is no express, implicit, or inherent disclosure to support all substances consisting of amino acids as instantly claimed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-18 and 20-21 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have been amended to read upon a composition comprising a ground powdered composition/formulations comprising a ground powdered composition.

Claims 15-18 and 20-21 recites the limitation “said composition is combined with suitable excipients or diluents or combination thereof”. There is insufficient antecedent basis for these limitation in the claims, because the claims recites a composition comprising a co-ground powdered composition, but the terms “excipients” and “diluents” include non-powder species, including water (see Examples 5, 6) and dimethicone emulsions (see Examples 6, 12) which would clearly create a composition which is not a powder. Furthermore, the species of *lotions, creams, ointments, pastes, gels, sticks, capsules, tablets, solutions, suspensions, and sprays* are clearly not ground powders or compositions comprising ground powders. Thus, there is insufficient antecedent basis for these limitations in the claims.

Claims 1-11, 15-18, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because the term “quaternary” is internally inconsistent with a composition *comprising* the recited chemical components. The terms are unclear because said

terms recite a closed (quaternary/consisting) and open (comprising) terms in the same claim.

Each is a reasonable interpretation of the claims, and one would not be apprised as to the subject matter Applicant intends by the claims, thereby rendering the claims indefinite.

For the sakes of compact prosecution the claims have been treated as a composition comprising the recited components; however, please note, this does not absolve Applicant of the requirement to appropriately address this ground of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 15-18, 20, and 21 are/remain rejected under 35 U.S.C. 103(a) as being obvious over AGA (A: PTO-892, 2/1/2007) in view of MANDAI (US 6,005,100 A) and ZAFFARONI (US 3,876,816 A) and KASORI (JP 60188036 A as evidenced by Derwent Abstract).

The claims have been amended to recite a quaternary co-ground powdered composition.

Applicant has argued that the motivation to combine/substitute glycyrrhizate and trehalose is based on a different intended use (flavor) than instantly claimed (co-grinding substance). Applicant has also argued that each of the references do not teach glycyrrhizate as a co-grinding substance or a glycyrrhizate-amino acid increased solubility synergy.

Applicant's arguments have been fully considered but, respectfully, they are not persuasive for the reasons of record and for the following reasons.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that the composition made obvious in view of the prior art provides a different intended use of the composition, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure (composition) is capable of performing the intended use (e.g. having solubility), then it meets the claim. Please note Mandai, Zaffaroni, and Kasori provide for the motivation for substituting glycyrrhizate and trehalose and AGA further provides the motivation for pulverizing (grinding) the powdery composition. Also as evidenced by CRC ("Physical Constants of Organic Compounds", in *CRC Handbook of Chemistry and Physics, 88th Ed. (Internet Version 2008)*, David R. Lide, ed., CRC Press/Taylor and Francis, §3, 1 page.), both

glycyrrhizate and trehalose are very soluble in water and thus would be expected to contribute to the intrinsic solubility of the bulk composition (i.e. compositions comprising the compounds), including ground compositions thereof.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., glycyrrhizate-amino acid synergy) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore to the extent the results are alleged to be unexpected/synergistic, the providing a very water-soluble compound (e.g. glycyrrhizate, trehalose) to a composition having a degree of water-solubility, to the contrary, would be expected to positively affect/increase water-solubility of the bulk composition. Also, as argued *supra*, said property of solubility is an aqueous property and thus compositions having similar chemical combinations and physical (powdered) form, would be expected to intrinsically have the claimed properties, especially in the absence of evidence to the contrary, side by side comparison(s), or evidence to the criticality of some undisclosed features.

Additionally, whereas the invention is alleged to be predicated on an unexpected result involving synergism, synergism is an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Thus, any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable. Accordingly, the instant claims, in the range of

proportions where no unexpected results are observed (e.g.- compositions other than those of table 1, examples 1 and 2), would have been obvious to one of ordinary skill having the above cited references before him.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion and the arguments of record, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary. Further, with regards to the synergistic effects of the compounds, it is noted that the features upon which applicant relies (i.e., a synergistic effect) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

For the reasons above and those of record the ground of rejection is maintained.

Double Patenting

It is noted that Application No. 10/515,097 has been abandoned. Consequently, the notice of provisional obviousness-type double patenting is withdrawn; however, the withdrawal is

contingent upon the abandoned 10/515,097 Application abandoned and thus remaining not co-pending with the instant Application.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. KOSAR whose telephone number is (571)270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1654

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ak/

Aaron Kosar

Examiner, Art Unit 1651

/Cecilia Tsang/

Supervisory Patent Examiner, Art Unit 1654